

REMARKS

The Official Action dated June 4, 2003 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification is amended to reference the U.S. priority application. Additionally, non-elected claims 44-51 and 53 are cancelled. It is believed that this represents a complete response to the restriction requirement. Claims 13, 76, 81, 83 and 84 have been rewritten in independent form. Claim 10 has been amended to correct an informality and claim 64 has been amended to more clearly define the invention in accordance with the teachings in the specification. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

The Examiner's indication of allowable subject matter in claims 13, 76 and 81-89 is acknowledged and appreciated. As noted above, claims 13, 76, 81, 83 and 84 are now presented in independent form. As claim 82 depends from 81 and claims 85-89 depend from claim 84, it is believed that all of claims 13, 76 and 81-89 are now prima facie allowable. Reconsideration is respectfully requested.

In the Office Action Summary, items 9) and 10), the specification and drawings were objected to by the Examiner. However, no further comments concerning any particular objections were provided in the Official Action. Four sheets of formal drawings are presented herewith to replace the informal drawings originally filed in the application. Accordingly, withdrawal of the objections or an indication as to the basis for the objections is requested.

Claim 10 was objected to on the basis that there was insufficient antecedent basis for recitation of "the opening duct". Claim 10 has been amended to correct this informality. Reconsideration is respectfully requested.

Claims 1-4, 6-12, 14-17, 19-21, 24, 27, 28, 30-37, 40, 54-57, 59, 60, 62, 63 and 92 were rejected under 35 U.S.C. §102(b) as being anticipated by the Scherer published PCT application WO 96/06581 (WO '581). The Examiner asserted that WO '581 teaches a pressurisable container comprising a front wall 208 with an opening 210 and a rear wall 206 closing and sealing the open part of the front wall. The Examiner further asserted that the rear wall 206 runs at least partially perpendicular to the container axis and is displaceably deformable for movement towards the opening to pressurize the container liquid, with the front wall substantially rigid in relation to the rear wall and the rear wall before pressurizing being substantially flat or single curved and deformable under stretching to substantially fill up the container cavity. The Examiner particularly referred to Figs. 11-13. With respect to method claims 54-57, the Examiner referred to page 7, lines 1-10 of WO '581.

However, as set forth in detail below, Applicants submit that the containers defined by claims 1-4, 6-12, 14-17, 19-21, 24, 27, 28, 30-37 and 40, the methods for ejecting liquid from a container defined by claims 54-57, 59, 60, 62 and 63, and the kit defined by claim 92 are not anticipated by and are patentably distinguishable from WO '581. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, independent claims 1 and 40 are directed to pressurizable containers for storing and ejecting a liquid. According to the invention, the container comprises a front wall having or surrounding a cavity corresponding to the form of an open vessel, an opening in the front wall adapted for ejection of the liquid from the container, the opening defining a container axis, optionally a sealing over the opening adapted for temporary use, and a rear wall closing and sealing the open part of the front wall vessel to

confine a space for the liquid in the container. The rear wall runs at least partially perpendicular to the container axis and is displaceable or deformable for movement towards the opening to pressurize the container liquid. According to claim 1, the front wall is substantially rigid in relation to the rear wall, the rear wall before pressurizing the container is substantially flat or substantially single curved, and the rear wall is deformable under stretching to substantially fill out the container cavity. According to claim 40, in the vicinity of the cavity, the front wall has the overall shape, except for the cavity itself, of a flat or single-curved plate with substantially parallel or concentric front and rear surfaces, at least a part of the cavity is formed between the front and rear surfaces with the opening exposed on the front surface and the open part of the vessel exposed on the rear surface, and the rear wall is attached to the rear surface.

Attention is directed to the present specification at page 5, beginning at line 13, wherein the term "single-curved" is defined as any form of a plane or surface obtainable from the same plane in flat form, without stretching or shrinking any part thereof in any direction within the plane, i.e., with maintained total surface for both the whole plane and any part thereof. In contrast, a "double-curved" plane or surface can only be obtained from a flat plane if deformed by stretching or shrinking. As further set forth in the specification, non-limiting examples of single-curved shapes include a cylinder surface or a corrugated surface as they can be formed from a non-elastic sheet by pure bending. In contrast, the surface of a sphere or saddle cannot be so formed without stretching and, accordingly, these shapes are double-curved.

WO '581 discloses an ocular treatment device which, as shown in Figs. 11-13 referenced by the Examiner, has a "double dome" construction (see, for example, WO '581 at page 15, line 12) which comprises a first dome 206 and a second dome 210. Therefore, contrary to the Examiner's assertion, the WO '581 containers do not have a rear wall which,

before pressurizing the container, is substantially flat or substantially single-curved as required by claim 1. Rather, the rear wall is dome-shaped and therefore double-curved. Similarly, the WO '581 containers do not have a front wall having an overall shape of a flat or single-curved plate with substantially parallel or concentric front and rear surfaces as required by claim 40. Rather, the front wall of the WO '581 containers is dome-shaped and therefore double-curved.

While Fig. 12C of WO '581 discloses the use of an intermediate layer 214, one of ordinary skill in the art will readily appreciate that such an intermediate layer cannot serve as either the front wall, as it has no opening, nor the rear wall, as it is neither displaceable nor deformable to pressurize container liquid.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of WO '581 to teach a pressurisable container having a rear wall which, before pressurizing the container, is substantially flat or substantially single curved, as required by claim 1, or a front wall having the overall shape, except in the vicinity of the cavity itself, of a flat or single-curved plate, as required by claim 40, WO '581 does not disclose each and every element as set forth in the claims. Thus, WO '581 does not anticipate claims 1 or 40, or claims 2-4, 6-12, 14-17, 19-21, 24, 27, 28, 30-37, 40, or 92 dependent thereon, under 35 U.S.C. §102.

Independent claim 54 is directed to a method for ejecting liquid from a container comprising a front wall having or surrounding a cavity corresponding to the form of an open vessel, an opening in the front wall adapted for ejection of the liquid from the container, the opening defining a container axis, optionally a sealing over the opening adapted for temporary use, and a rear wall closing and sealing the open part of the front wall vessel to confine a space for the liquid in the container. The rear wall runs at least partially

perpendicular to the container axis and is displaceable or deformable for movement towards the opening to pressurize the container liquid. The method comprises pressurizing the container by moving the rear wall at least partially in the axial direction and towards the opening with sufficient speed to eject liquid through the opening and hereunder stretching the rear wall, elastically or inelastically, to increase its surface.

Applicants find no teaching by WO '581 relating to such a method, and particularly including any step wherein a rear wall is stretched, elastically, i.e., retractably, or inelastically, i.e., non-retractably, to increase its surface. Although the Examiner referred to page 7, lines 1-10 of WO '581, Applicants find no such teaching at this portion of the reference. Particularly, WO '581 discloses at page 7, lines 1-10 that the enclosure may be crushed from the side opposite the wall section by a piston, hammer or cantilever mechanism to discharge and project the contents, or the enclosure may be formed as a cylindrical chamber with an opposite wall portion formed as a piston for movement towards the wall section to force the enclosure contents through the opening. However, this provides no teaching of a method as recited in claim 54 wherein the rear wall is moved at least partially in the axial direction and towards the opening with sufficient speed to eject liquid through the opening and is hereunder stretched, elastically or inelastically, to increase its surface.

In view of the failure of WO '581 to teach such a process, WO '581 does not disclose each and every element of claim 54 or claims 55-57, 59, 60, 62, or 63 dependent thereon. Thus, WO '581 does not anticipate these claims under 35 U.S.C. §102.

It is therefore submitted that the rejection under 35 U.S.C. §102 based on WO '581 has been overcome. Reconsideration is respectfully requested.

Claims 1, 5, 14, 18, 19, 20-26 and 42 were rejected under 35 U.S.C. §102(b) as being anticipated by the Lloyd et al U.S. Patent No. 5,709,202. The Examiner asserted that Lloyd

et al teach a pressurizable container 16 having a front wall with an opening 13 and a rear wall 14 which is substantially flat or substantially single curved. The Examiner referred to Fig. 3.

However, Applicants submit that the containers defined by claims 1, 5, 14, 18, 19, 20-26 and 42 are not anticipated by and are patentably distinguishable from Lloyd et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The container of claim 1 is discussed in detail above. Claim 42 is directed to a pressurisable container for storing and ejecting liquid. The container comprises a front wall having or surrounding a cavity corresponding to the form of an open vessel, an opening in the front wall adapted for ejection of the liquid from the container, the opening defining a container axis, optionally a sealing over the opening adapted for temporary use, and a rear wall closing and sealing the open part of the front wall vessel to confine a space for the liquid in the container. The rear wall runs at least partially perpendicular to the container axis and is displaceable or deformable for movement towards the opening to pressurize the container liquid. The front wall thickness, as measured along lines running through the cavity and normal to the vessel closed surface, increases in a direction off-set from the container axis.

Lloyd et al disclose a dispensing device capable of individually opening dosage unit containers and aerosolizing the contents through a nozzle for delivery to a patient. The container 14 set forth in Fig. 3 of Lloyd et al referred to by the Examiner includes two compartments 15 and 16. The compartment 15 is bound by flexible accordion walls 17 while the compartment 16 includes cylindrical walls 18 which may be rigid or flexible, and the compartments are separated by a wall 19 which includes a weakened portion 20 which can be ruptured by the application of additional pressure. The compartment 15 includes a driving gas while the compartment 16 holds a liquid to be dispensed.

However, the pressurizable containers recited in claims 1 and 42 are significantly distinguishable from the container 14 of Lloyd et al. That is, the rear wall of the Lloyd et al

container does not close and seal the open part of the front wall vessel to define a space for liquid in the container, as is required in claims 1 and 42. To the contrary, the rear wall of compartment 15 engages accordion side walls 17, and the rear wall 20 of compartment 16 engages side walls 18. Moreover, in the Lloyd et al container, the gas in compartment 15 expels the liquid from the container. In contrast, claims 1 and 42 require that the rear wall is displaceable or deformable to pressurized the container liquid. Additionally, the portion of the Lloyd et al container which is to be deformed is the compartment 15, including the accordion side walls 17 and thus is not substantially flat or substantially single-curved and is not deformable under stretching to fill out the container cavity, as further required by claim 1. In view of these differences, Lloyd et al do not disclose each and every element as set forth in claims 1 and 42. Thus, Lloyd et al do not anticipate claims 1 or 42, or claims 5, 14, and 18-26 dependent thereon, under 35 U.S.C. §102, *In re Robertson, supra*. It is therefore submitted that the rejection under 35 U.S.C. §102 based on Lloyd et al has been overcome. Reconsideration is respectfully requested.

Claims 1 and 29 were rejected under 35 U.S.C. §102(b) as being anticipated by the Bergerioux U.S. Patent No. 2,208,744. The Examiner referred to Fig. 2 as disclosing a container comprising a front wall 1 and a rear wall 3 closing and sealing the open part of the front wall vessel wherein the front is substantially rigid in relation to the rear wall and the rear wall is substantially flat or substantially single curved and deformable under stretching to substantially fill out the container cavity.

However, Applicants submit that the containers defined by claims 1 and 29 are not anticipated by and are patentably distinguishable from Bergerioux. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The container of claim 1 is discussed in detail above. While Bergerioux discloses a container with a flexible diaphragm for dispensing materials, Applicants find no teaching in

this reference that the diaphragm, before pressurizing, is substantially flat or substantially single curved, or that the diaphragm is deformable under stretching to substantially fill out the container cavity, as is required in the pressurizable container of claim 1. More particularly, the diaphragm 3 of Bergerioux is disclosed as having an initial configuration "a" corresponding to that of the permanent portion (see, for example, page 1, right column, lines 14-15). It is apparent from Fig. 1 that the initial configuration "a" is of a double-curved shape, i.e., spherical as shown in Fig. 1 or closed cylindrical as shown in Fig. 7, rather than of the flat or single-curved configuration required by claim 1. In a second step, the diaphragm of Bergerioux is deformed into a second configuration "b" which may take different shapes as shown in various figures, but which is capable of returning to the initial configuration "a" to empty the container (see, for example, page 1, right column, lines 20-24 and page 2, left column, lines 13-18). Consequently, the diaphragm, while flexible, is not deformable under stretching to substantially fill the container cavity as required by claim 1. Figs. 2 and 5 show the diaphragm as having "irregular wrinkles" with "concentric tendency" and "concentric elements" (page 1, right column, lines 46-53), which are a result of the initial double curve configuration "a". In contrast, the embodiment of Fig. 1A in the present specification has straight folds created from flat material, as described at page 18, lines 23-37 of the present specification.

In view the failure of Bergerioux to teach a pressurisable container having a rear wall which is, before pressurizing, substantially flat or substantially single curved, or which is deformable under stretching to substantially fill out the container cavity, Bergerioux does not disclose each and every element as set forth in claims 1 and 29. Thus, Bergerioux does not anticipate claims 1 or 29 under 35 U.S.C. §102, *In re Robertson, supra*. It is therefore submitted that the rejection under 35 U.S.C. §102 based on Bergerioux has been overcome. Consideration is respectfully requested.

Claims 38, 39, 58, 61, 93, 94, 96 and 97 were rejected 35 U.S.C. §103 as being obvious and unpatentable over WO '581. The Examiner asserted that the structural dimension and test characteristic limitations of these claims do not support patentability.

However, Applicants submit that the containers defined by claims 38, 39, 93, 94, 96 and 97 and the methods defined by claims 58 and 61 are nonobvious over and patentably distinguishable from WO '581. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, claims 38, 39, 93, 94, 96 and 97 depend from claim 1 while claims 58 and 61 depend from claim 54. The deficiencies of WO '581 with respect to the container of claim 1 and the method of claim 54 are discussed in detail above. Specifically, WO '581 fails to teach a pressurisable container having a rear wall which, before pressurizing the container, is substantially flat or substantially single curved, as required by claim 1, and fails to teach a method including any step wherein a rear wall is stretched, elastically or inelastically, to increase its surface to eject a liquid from a container as required by claim 54. Moreover, Applicants find no suggestion by WO '581 for modifying any of the teachings set forth therein along the lines of the container of claim 1 or the method of claim 54.

The mere fact that prior art could have been modified to result in a claimed invention would not have made the modification obvious unless the prior art suggested the desirability of the modification, *In re Mills*, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Applicants find no suggestion of any such desirability for modifying any of the teachings of WO '581 to result in the claimed containers or methods. In view of these deficiencies in the teachings of WO '581, one of ordinary skill in the art would have no motivation or desire to arrive at the specific structural limitations of claims 38, 39, 93, 94, 96 and 97, or the specific ejection method requirements of claims 58 and 61. Thus, contrary to the Examiner's assertion, neither the limitations of the rejected claims, nor the limitations of claims 1 and 54 from which they

depend, are suggested by or rendered obvious over WO '581. Thus, the rejection under 35 U.S.C. §103 based on WO '581 has been overcome. Reconsideration is respectfully requested.

Finally, claims 64-75 and 77-80 were rejected as being obvious and unpatentable over Lloyd et al. The Examiner referred to Figs. 7 and 9 of Lloyd et al and to elements in Fig. 5 of Lloyd et al.

However, Applicants submit that the devices for ejecting liquid from a container defined by claims 64-75 and 77-80 are nonobvious over and patentably distinguishable from Lloyd et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

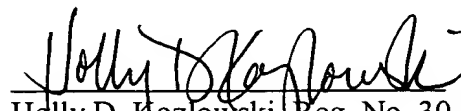
Claim 64 is directed to a device for ejecting liquid from a container, the container comprising a front wall having or surrounding a cavity corresponding to the form of an open vessel, an opening in the front wall adapted for ejection of the liquid from the container, the opening defining a container axis, optionally a sealing over the opening adapted for temporary use, and a rear wall closing and sealing the open part of the front wall vessel to confine a space for the liquid in the container. The rear wall runs at least partially perpendicular to the container axis and is displaceable or deformable for movement towards the opening to pressurize the container liquid and substantially fill out the container cavity. The device further comprises a housing with a seat for the container adapted to receive a container having a distance between rear wall and front wall front surface of at least 0.5 mm, a ram arranged in a moving direction, in relation to the housing, substantially axial to the container when in the seat, and an actuator operative to drive the ram. Thus, the ram will displace or deform the rear wall of the container for movement towards the opening to pressurize the container liquid and substantially fill out the container cavity.

Lloyd et al disclose a dispensing device capable of individually opening dosage unit containers and aerosolizing the contents through a nozzle for delivery to a patient. As described at column 30, lines 20-65, in the embodiment shown in Fig. 7 of Lloyd et al, and in Fig. 8 of Lloyd et al, the container does not have a front wall having or surrounding a cavity corresponding to the form of an open vessel. That is, the front wall 72 merely seals a container formed by sidewalls and rear wall 71. Accordingly, when the piston 75 is actuated, the container collapses. In contrast, in the device of claim 64, the rear wall, rather than the entire container, is displaceable or deformable by the ram for movement towards the opening to pressurize the container liquid and substantially fill out the container cavity, and, consequently, sidewalls of the container are not crushed or deformed.

In order to render a claimed invention obvious, the prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). In view of the deficiencies in the teachings of Lloyd et al with respect to a container rear wall and ram as required by claim 64, Lloyd et al do not enable one of ordinary skill in the art to make the device of claim 64. Thus, Lloyd et al do not render the device of claim 64, or claims 65-75 and 77-80 dependent thereon, obvious. Thus, the rejection under 35 U.S.C. §103 based on Lloyd et al has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102 and 103 and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



Holly D. Kozlowski, Reg. No. 30,468
Dinsmore & Shohl LLP
1900 Chemed Center

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255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568